IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 23-cv-0685-CFC **ANDA CASE**

MEMORANDUM

This patent infringement case arises out of the submission by Defendants (collectively, Apotex) of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) for approval to market a generic version of Tradjenta®, a pharmaceutical that is orally administered in tablet form to treat patients with type 2 diabetes mellitus. Tradjenta® is marketed by Plaintiffs (collectively, Boehringer). The active pharmaceutical ingredient in Tradjenta® is linagliptin. Boehringer alleges that Apotex's submission of its linagliptin ANDA

constitutes infringement of two of Boehringer's U.S. patents—Nos. 9,486,526 and 10,034,877—under § 271(e)(2)(A) of the Patent Act, 35 U.S.C. § 1 *et seq*.

Pending before me is Apotex's motion pursuant to Federal Rule of Civil Procedure 12(c) for judgment on the pleadings. Such a motion "should be granted if the movant establishes that there are no material issues of fact, and [the movant] is entitled to judgment as a matter of law." *Zimmerman v. Corbett*, 873 F.3d 414, 417 (3d Cir. 2017) (internal quotation marks and citation omitted). "In considering a motion for judgment on the pleadings, a court must accept all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw all reasonable inferences in favor of the non-moving party." *Id.* at 417–18 (citations omitted). A court may also look to documents "integral to or explicitly relied upon" in the pleadings. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (citation omitted). The parties agree that the asserted patents and the proposed label Apotex has submitted with its ANDA for FDA approval to market its generic version of linagliptin are integral to and explicitly relied upon in the pleadings. *See* D.I. 27 at 10–12; D.I. 35 at 8–9.

The asserted patents cover methods of treating type 2 diabetes mellitus using linagliptin in patients who have severe renal impairment and who, because they suffer from severe renal impairment, are contraindicated (i.e., ineligible) for being treated with the drug metformin. *See* D.I. 27 at 4–5; D.I. 35 at 5. Boehringer

accuses Apotex of actively inducing doctors to infringe the patents under § 271(b) of the Patent Act and contributing to the infringement of the patents under § 271(c). D.I. 1 ¶¶ 38–57. (Apotex argues in its briefing that it is also entitled to a judgment of no direct infringement as a matter of law, D.I. 27 at 12–13, but the Complaint does not allege that Apotex directly infringed the asserted patents. *See generally* D.I. 1.)

To prove that a defendant actively induces infringement, the plaintiff must establish that the defendant committed an "affirmative act of some kind" to "cause[], or urge[], or encourage[], or aid[] another to infringe a patent." *Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376, 1378–79 (Fed. Cir. 2001) (citation omitted). Apotex argues that it is entitled to a judgment of no induced infringement as a matter of law because its proposed label does not instruct, promote, or otherwise encourage doctors to use its ANDA product to treat patients who are ineligible for being treated with metformin. D.I. 27 at 2–3, 13–15.

There is much in the label that supports Apotex's argument, and I would not be surprised if Apotex prevailed on this noninfringement theory at a trial. The proposed label states broadly under the heading "Indications and Usage" that "[l]inagliptin tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." D.I. 15-3 at 3. And it specifically and repeatedly teaches in its discussion of various clinical trials that

Apotex's ANDA product can be used *in combination with* metformin and *as an add-on therapy to* metformin. *See* D.I. 15-3 at 4, 5, 10–19. In other words, there are many statements in the proposed label that on their face appear to promote and encourage doctors to use Apotex's ANDA product to treat patients who are *eligible* for treatment with metformin—that is, to use a treatment method that is the very opposite of the method claimed by the asserted patents.

There is, however, a sentence in section 8.6 of Apotex's proposed label that states: "No dosage adjustment is recommended for patients with renal impairment[.]" D.I. 15-3 at 7. And the proposed label cites in support of this statement and discusses in some detail data from the so-called CARMELINA clinical trial study in which linagliptin was administered to 2,200 patients, 15% of whom suffered from severe renal impairment. D.I. 15-3 at 7, 18–19. It is undisputed that patients who suffer from severe renal impairment are ineligible for metformin. *See* D.I. 27 at 7. For that reason, and drawing all reasonable inferences in Boehringer's favor, the discussion of the CARMELINA study coupled with the "[n]o dosage adjustment is recommended for patients with renal impairment" statement provides a not unreasonable basis for Boehringer to argue at trial that Apotex intends to use its proposed label to promote and encourage doctors to use its ANDA product to treat patients with type 2 diabetes mellitus who

are ineligible for being treated with metformin. A factual dispute therefore exists that precludes entry of judgment of no induced infringement as a matter of law.

"To establish contributory infringement, the patent owner must show . . . : 1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the component has no substantial noninfringing uses, and 4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). "[N]on[]infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). "In a pharmaceutical case, the noninfringing use must be in accordance with the use for which the product is indicated." *Grunenthal GmbH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1340 (Fed. Cir. 2019).

Apotex argues that because its ANDA Product is "suitable for administration to diabetes patients who are *eligible* for metformin," Boehringer cannot make a showing that Apotex's ANDA Product has no substantial noninfringing use. D.I. 27 at 20 (emphasis in the original). Boehringer does not dispute that Apotex's product is suitable for the noninfringing use of treating patients who are eligible for metformin. Its only counterargument is that "[s]ubstantial noninfringing use is an intensely factual inquiry not suitable for determination at the pleading stage." D.I. 35 at 21. Boehringer insists that whether Apotex's ANDA has a substantial

noninfringing use is a disputed fact because I "must credit Boehringer's allegations that Apotex's generic product 'is not [a] staple article[] of commerce or commodit[y] of commerce suitable for substantial noninfringing use.'" D.I. 35 (citing D.I. 25 ¶¶ 75–80) (alterations in the original). Those "allegations," however, even if true, are of no moment. The law does not require that a drug be a "staple article of commerce" to qualify for a substantial noninfringing use. As noted above, the noninfringing use of Apotex's ANDA product need only be in accordance with the use for which it is indicated and not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental to qualify as "substantial noninfringing use." As it is undisputed that the use of Apotex's ANDA product to treat patients with type 2 diabetes mellitus who are eligible for being treated with metformin is in accordance with the use for which it is indicated by Apotex's proposed label and not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental, Apotex is entitled to judgment of no contributory infringement as a matter of law.

I will therefore DENY Apotex's motion insofar as it seeks judgment of no induced infringement as a matter of law and GRANT the motion insofar as it seeks judgment of no contributory infringement as a matter of law.

The Court will enter an order consistent with this Memorandum.

1.10.25
DATE

CHIEF JUDGE